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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,076	02/06/2004	Nicholas F. Landolfi	05882.0064.NPUS01	7347

47470 7590 08/22/2005

LEGAL DEPARTMENT
PROTEIN DESIGN LABS, INC.
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FREMONT, CA 94555

EXAMINER

KIM, YUNSOO

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/774,076

Applicant(s)

LANDOLFI ET AL.

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Examiner

Yunsoo Kim

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 30 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13-15, 18-25, 28 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-10, 13, 14, 18-25, 28 and 32 is/are rejected.
- 7) ☒ Claim(s) 2-4, 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Detailed Action

1. Applicant's amendment, filed 6/30/05 is acknowledged.
Claims 1-3, 8-10, 18, 22-23, and 25 have been amended.
Claims 16, 19 and 26 have been cancelled.
Claims 1-10, 13-15, 18, 20-25, 28 and 32 are pending.
2. In view of Applicants' cancellation and amendments to the claims, objections (sections 7-8), and rejections (section 10, 11 and 16-18) set forth in the previous office action mailed on 3/11/05 have been withdrawn.
3. Claims 2-4 and 15 are objected by being depended upon rejected claim.
4. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 1, 5-10, 13-14, 18-25, 28 and 32 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a chimeric or human antibody that competitively inhibits binding of an amphiregulin (AR) peptide to anti-AR antibody that consists of SEQ ID NOs: 2, 3, 4, 5, 12 or 14 to treat psoriasis, does not reasonably provide enablement for any antibodies that competitively inhibit binding of an AR comprises SEQ ID NO:1 and amino acid sequence comprising of SEQ ID NO: 2, 3, 4, 5, 12, or 14 to treat cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants' arguments filed on 6/30/05 have been fully considered but they are not persuasive.

Currently amended claim 1 is considered open and encompasses amphiregulin sequence to any amino acid sequences comprising SEQ ID NO:1 which includes any peptides of any lengths.

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The claim 1 does not recite a combination of heavy chain and light chain which is required for antigen binding.

It was well known at the time of the invention and current state of art as demonstrated by Janeway (Immunobiology, 6th Edition, 2004, Garland Science, p. 110-112). Janeway et al. teach that all of the heavy and light chain CDRs in their proper order and in the context of framework sequences which maintain their required conformation are required in order to produce a protein having antigen binding function and that proper association of heavy and light chain variable regions is required in order to form functional binding sites.

6. Claims 1, 5-10, 13-14, 18-25, 28 and 32 stand rejected under 35.U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed, had possession of the claimed invention for the same reasons set forth in the previous action mailed 3/11/05.

Applicant's arguments filed on 4/1/05 have been fully considered but they are not persuasive.

As stated in the previous office action and the "comprising" language in claims considered open, Applicant is not in possession of any anti-AR antibody "comprising" the amino acid sequence of the SEQ ID NOs: 2, 3, 4, 5, 12, or 14. Since SEQ ID NOs: 2, 3, 4, 5, 12 and 14 are Vh and Vl sequences, applicant is invited to limit addition of constant region of heavy chain and light chain to said SEQ ID NOs.

7. It is noted that claims drawn to the following antibodies would appear to be free of the art:

- 1) an antibody comprising the heavy chain variable region defined by SEQ ID NO:2 and the light chain variable region defined by SEQ ID NO:3;
- 2) an antibody comprising the heavy chain variable region defined by SEQ ID NO:4 and the light chain variable region defined by SEQ ID NO:5; and
- 3) an antibody comprising a heavy chain variable region defined by SEQ ID NO:12 and a light chain variable region defined by SEQ ID NO:14.

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8. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

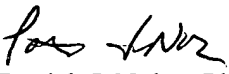
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
Patent Examiner
Technology Center 1600
August 17, 2005


Patrick J. Nolan, Ph.D.
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